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Dated: December 28, 2006

Signature: 

JIE ZHOU

Docket No.: 415072002300
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jennie P. MATHER et al.

Application No.: 10/713,248

Confirmation No.: 1169

Filed: November 13, 2003

Art Unit: 1643

For: ANTIGEN PIPA AND ANTIBODIES THAT
BIND THERETO

Examiner: A. Holleran

DECLARATION UNDER 37 C.F.R. § 1.132

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Tony W. Liang, declare as follows:

1. I received B.A. in Molecular Biology/Biochemistry from Boston University. I have had over 12 years of experience working with antibodies in the field of protein chemistry. I am an inventor on 2 pending patent applications and an author on 11 publications. I am currently a Scientist at Raven biotechnologies, inc.
2. I am an inventor of the invention that is the subject of the above referenced patent application (hereinafter "the Application"), and am familiar with the contents of that Application.

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3. Monoclonal antibodies such as the ones referenced in the Application recognize and bind to antigen targets. Recognition and binding to an antigen target can affect the bioactivity and function of the antibody and the target they recognize.
4. Antibody ELISA assays using purified antigen can effectively determine an antibody's antigen target.
5. A standard antibody ELISA assay, such as the one used in Exhibit 1 to illustrate binding of an antibody to the antigen target CD48, consists of the following steps:
 - (a) Coat purified protein target (recombinant human CD48, R&D Systems) onto a 96-well plate;
 - (b) Block wells with 1% BSA in Hank's Balanced Salt Solution.
 - (c) Incubate protein target CD48 coated to the 96-well plate with primary antibody:
 1. PIP;
 2. anti-CD48 antibody positive control (Goat anti-human CD48), ; or
 3. mouse IgG negative control antibody;
 - (d) Wash 3 times with a wash buffer (Hank's Balanced Salt Solution, no phenol red, no sodium bicarbonate, with 10 mM HEPES, pH 7.4);
 - (e) Incubate with a secondary antibody:
 1. For PIP and negative control conditions, a goat anti-mouse HRP conjugated antibody was used;
 2. For the positive control condition, a mouse anti-goat HRP conjugated antibody was used;
 - (f) Wash 3 times with wash buffer;
 - (g) Develop using 3,3', 5, 5' - Tetramethylbenzidine;
 - (h) Neutralize with 1M phosphoric acid;
 - (i) Read on plate reader at O.D. 450nm.

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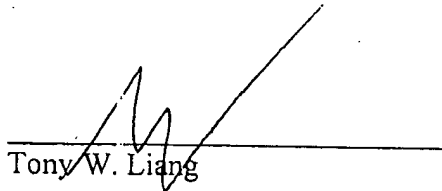
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6. We investigated whether the antigen target of the PIP antibody was CD48 using the protocol described in Paragraph 5 above. Recombinant human CD48 and an anti-CD48 monoclonal antibody used as a positive control were purchased from R&D Systems. Exhibit 1 shows the results of the antibody ELISA assay.
7. As shown in Exhibit 1, the PIP antibody and the negative control antibody did not bind to recombinant CD48. In contrast, the positive control antibody showed a strong signal against the recombinant CD48. This indicates that the PIP antibody does not bind to CD48. Thus, the antigen target for the PIP antibody is not CD48.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: December 28, 2006


Tony W. Liang

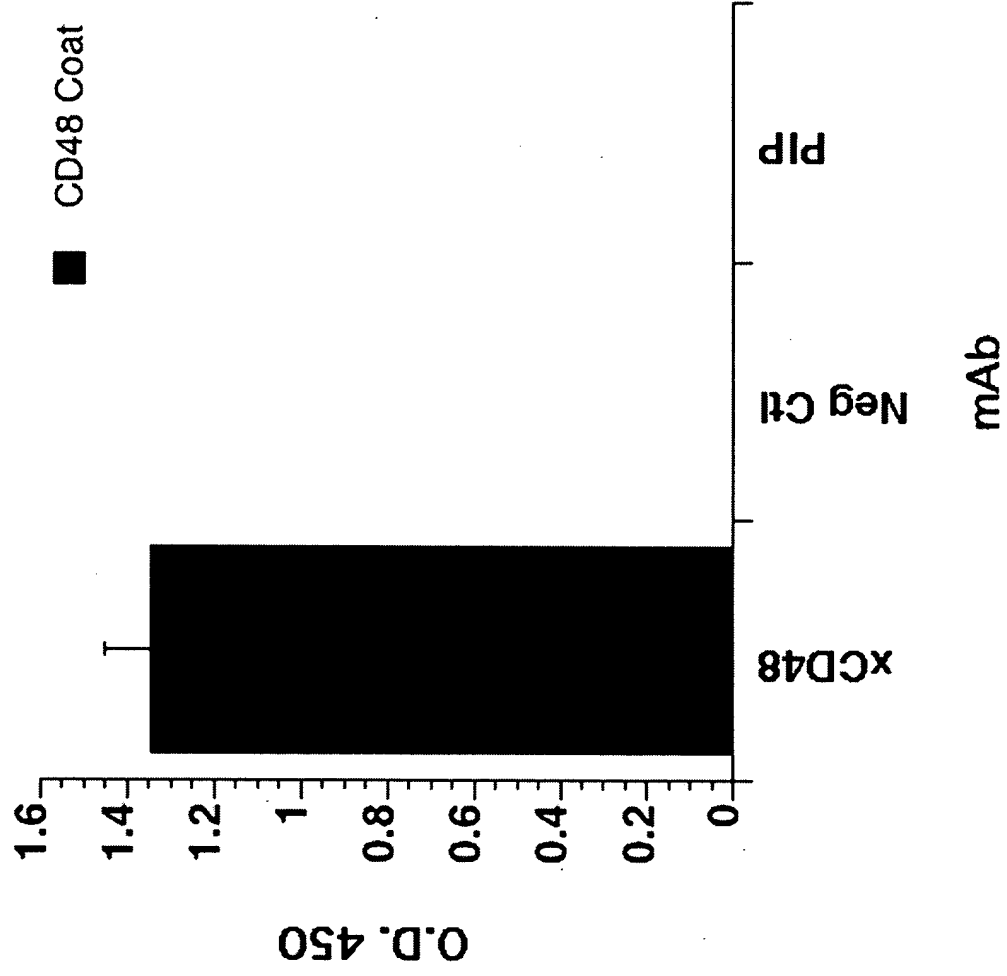


Exhibit 1